

PO Box 242
Forestville, CA 95436

FARMACY

8561 '99 JUN -1 P137

May 27, 1999

DOCKET'S MANAGEMENT BRANCH
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

Dear Sir or Madam:

Please find a "Petition and Notice of Exemption" pursuant to 21 CFR 314.200(e)(2). Upon receipt and filing, please send notification of the filing and document number to the address noted above.

Thank you in advance for your courtesy and cooperation in this matter. Should you have any questions or comments, do not hesitate to contact me at (707) 568-0945.

Sincerely,



Paul Kloppe

99P-1865

CP 1

1 TO: DOCKETS MANAGEMENT BRANCH
2 Food and Drug Administration
3 Department of Health and Human Services
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

8562 '99 JUN -1 P1:37

4
5 **PETITION and NOTICE OF EXEMPTION**
6

7 The undersigned, Paul Kloppe - doing business as Farmacy,
8 and Dr. Tod H. Mikuriya, M.D., submit this petition and notice of
9 exemption under 21 U.S.C. § 321(p) to request the Commissioner of
10 Food and Drugs to issue a ruling that the products listed below
11 are exempt from all of the new drug provisions of the act under
the exemption for products marketed before June 25, 1938 (more
commonly known as the "grand-father clause"). See 21 CFR §
314.200(e) (2)

12 **A. PRODUCTS SUBJECT TO EXEMPTION**

- 13 1. Flowering Tops, prepared from Home-Grown Cannabis (HGC)
14 2. Powdered Extract, prepared from HGC
15 3. Solid Extract, prepared from HGC
16 4. Fluid Extracts, prepared from HGC
17 5. Tinctures, prepared from HGC
18 6. Pressed Flowering Tops, prepared from HGC
19 7. Ground Flowering Tops, prepared from HGC
20 8. Oil with Infused Tops, prepared from HGC
21 9. Tablets, prepared from HGC
22 10. Chocolate coated tablets, prepared from HGC
23 11. Pill and/or Capsule, prepared from HGC
24 12. Pilular Extract, prepared from HGC
25 13. Poultice, prepared from HGC

26 **B. FORMULATIONS, USES, LABELING, and MARKETING**

27 Attached hereto are copies of pertinent documents and
28 records that establish the formulations, the uses, the labeling,
and the marketing of the above identified products at the time of
the initial marketing of those products. These documents and/or
records are best summarized as follows:

29 **PARKE, DAVIS & CO.**

30 From 1890 through 1937, the Parke, Davis & Company widely
31 marketed various formulations of medical cannabis. The products
32 and formulations were advertised as originating from "home-grown
33 cannabis." Parke, Davis & Company marketed tinctures and fluid
34 extracts sold by the pint or fluid ounce; cannabis tablets and
35 pills sold by the gram; solid and powdered extracts sold by the

1 gram, ounce, or pound; and "pressed flowering tops" also sold by
2 the gram, ounce, or pound. Solid and powdered extracts along
3 with "flowering tops" were sold to practitioners or ultimate
users who wished to prepare their own tinctures, fluids, or
tablets.

4 The advertised uses of these formulations include the
5 following: analgesic, sedative, corn cures, spasmodic disorders,
6 genito-urinary irritation, persistent cough, insomnia, hysteria,
asthma, delirium tremens, acute fevers, cathartics, migraine,
gastralgia, pruritus, neuralgia, and as a narcotic "used in place
of opium."

7
8 *ELI LILLY & COMPANY*

9 From 1877 through 1935, the Eli Lilly Company marketed
10 fluid, solid, and powdered extracts, all of which were
manufactured from the "flowering tops of the pistillate plants of
Cannabis sativa L."

11 The advertised uses include: antispasmodic, analgesic,
12 sedative, aphrodisiac, narcotic, delirium tremens, insanity,
hysteria, migraine.

13 *MERCK*

14 In the late 1800's to early 1900s, Merck manufactured and
15 sold the "flowering top of the female plant" by the pound. They
also sold, by the pound, tops that were "ground for percola" as
16 well as cannabis oil with "infused tops." In addition, Merck
sold fluid extracts, tinctures, and pilular extracts.

17 The Advertised uses included increase appetite, anodyne,
18 antispasmodic, and rheumatism.

19 *SQUIBB*

20 In the late 1800's to early 1900's, Squibb manufactured and
21 sold tinctures and tablets as well as "the dried flowering tops
of the female plant" which could be "ground for peccolation
(sic)."

22 The advertised uses include anodyne, epilepsy, hysteria,
23 sedative, neuralgic attacks.

24 *APEX/FEDERICK STEARNS & CO.*

25 Sometime prior to 1938, Apex and Federick Stearns marketed
26 a poultice (cannabis combined with alcohol and ether; cannabis
combined with salicylic acid and collodion). The advertised use
was for a Corn Remedy.

27 Upon information and belief, the formulations - identified
28 above as more fully set forth in the attached - have never been
changed. Those formulations and the marketing of those products
were discontinued on the dates noted above.

1 In addition to the commercial manufacturing and marketing of
2 these products, the medical journals of the time described these
3 products as follows:

4 *DISPENSATORY OF THE UNITED STATES OF AMERICA (1937)*

5 This describes cannabis as "the dried flowering tops of the
6 pistillate plants of *Cannabis sativa* Linne" and then further
7 describes cannabis in its various forms - unground flowers and
8 leaves, the stem, and powdered cannabis. American cannabis known
9 as "*Cannabis Americana*" is "yielded from the *Cannabis sativa*
10 plants cultivated in various sections of the United States." "It
11 occurs on the market in the form of broken segments of the
12 inflorescence and more or less crumpled and broken leaves,
13 varying in color from brownish-green to light brown."

14 "Only the female plant produces the drug" and "*Cannabis* is
15 used in medicine to relieve pain, to encourage sleep, to soothe
16 restlessness ... and will often relieve migranic headaches." The
17 text notes that "the only way of determining the dose of an
18 individual is to give it ascending quantities until some effect
19 is produced." The formulations noted are "exctractum,
20 fluidextractum, and tinctura."

21 *PHARMACOPOEIA OF THE UNITED STATES OF AMERICA (1926)*

22 This text describes cannabis as "the dried flowering tops of
23 the pistillate plants of *Cannabis sativa* Linne" and then explains
24 how to "assay" the fluidextract in gelatin capsules using dogs to
25 determine the appropriate strength.

26 *PHARMACOPOEIA OF THE UNITED STATES OF AMERICA (1936)*

27 This discusses "extratum cannabis": "Prepare an extract by
28 percolating 1000 Gm. of cannabis in moderately coarse powder,
using alcohol as the menstruum. ..." Eventually, the
practitioner/ultimate user will "evaporate the percolate to a
pilular consistence ..."

29 *MATERIA MEDICA: PHARMACOLOGY: THERAPEUTICS PRESCRIPTION WRITING
30 FOR STUDENTS AND PRACTITIONERS (1914)*

31 This text notes the various formulations; to wit, extract,
32 fluidextract, and tincture, and further notes that Dixon [a well
33 known British authority] "recommends inhalation of the vapor as
34 most soothing." Though "*Cannabis indica* is very little
35 employed", common usage include: "allaying nervous excitability,
36 pain of neuralgia or migraine, promoting sleep in the presence of
37 pain."

38 *MATERIA MEDICA AND PHARMACOLOGY (1927)*

39 This text details how to prepare the various extracts and
40 lists cannabis use for "neuralgia, distressing cough, quiets
41 tickling in throat, does not constipate or depress like opium,
42 gout, delirium tremens, tetanus convulsions, chorea, hysteria,

1 mental depression, epilepsy, morphine and chloral habits,
2 softening of the brain, nervous vomiting."

3 *THERAPEUTICS MATERIA MEDICA AND PHARMACY (1926)*

4 This explains that "cannabis and its preparations must be
5 standardized by physiological assay according to the U.S.
6 Pharmacopoeia. The assay is based upon the amount of drug which
7 is required to produce symptoms of incoordination in the dog."
8 The text also explains that "cannabis contains a resin named
cannabin" and there are solid extracts, fluid extracts, and
tinctures which are used as an "antispasmodic, analgesic,
anesthetic and narcotic, a cerebro-spinal stimulant and a powerful
aphrodisiac." "A ravenous appetite is usually one of its early
effect."

9 *POCKET THERAPEUTICS AND DOSE-BOOK (1910)*

10 Notes cannabis is available in tinctures and extracts and
11 also available is "cannabinon" - the "resin from Cannabis indica"
12 and "cannabin tannas" - "a powdered prepared from Cannabis
13 indica." The solid extract and the cannabinon and cannabin
tannas are available by the gram. Uses include antispasmodic,
anti neuralgic, anodyne, cough sedative in tuberculosis, and
migraine or sick headache."

14 Also included, but not separately summarized here, are
15 cannabis references found in: *Pharmacopoeia of the United States*
16 (1936), *Remington's Practice of Pharmacy* (1936), *A Text-Book of*
17 *Practical Therapeutics* (1916), *Textbook of Materia Medica* (1931),
and *Textbook of Materia Medica* (1928).

18 **C. RELEVANT STATUTORY, REGULATORY, and JUDICIAL DECISIONS**

19 The Administrator for the Drug Enforcement Agency has
20 recognized that formulations prepared from Cannabis were marketed
as medicine prior to 1938:

21 "Cannabis sativa L. was one of the first plants
22 to be used by man for fiber, food, medicine, and in
23 social and religious rituals. There were approximately
24 20 traditional medicinal uses of cannabis ... in
Western medicine from the mid-19th to the early 20th
century ... In 1941, marijuana passed out of the
National Formulary and the United States Pharmacopeia."

25 54 Fed.Reg. 53767, 53774 (1989).

26 The Controlled Substance Act, 21 U.S.C. § 801 et seq.,
27 currently lists "marihuana" as a schedule I substance. See 21
28 U.S.C. § 812(I)(c)(10). Petitioner contends Congress did not
"un-grandfather" the above listed products when it decided to
place "marihuana" (generally) into the schedule I category. At
the beginning of the statute setting forth the list of schedule

1 I substances, Congress declared its intent to recognize
2 previously grandfathered substances: "Unless specifically
3 excepted ... any material, mixture, or preparation, which
4 contains any quantity of the following ... (10) Marihuana." 21
5 U.S.C. § 812(I)(c).

6 The "unless specifically excepted" clause must be read to
7 refer to 21 U.S.C. § 321(p) which "excepted" and accepted as
8 medicine those products marketed prior to 1938. If Congress had
9 intended to repeal marijuana's pre-1938 exemption as cannabis
10 medicine under § 321(p), it would have made clear its intent to
11 repeal that exemption. *Tennessee Valley Authority v. Hill*, 437
12 U.S. 153, 189-90 (1978) ("intention of the legislature to repeal
13 must be clear and manifest.").

14 In *Rutherford v. United States*, 542 F.2d 1137, 1142n4. (10th
15 Cir.1976), the court notes that a pre-1938 product could be un-
16 grandfathered, but only when that previously grandfathered drug
17 is found to be "dangerous to health." To date, neither Congress,
18 the FDA, the DEA, nor the recently commissioned panel from the
19 Institute of Medicine (see *Marijuana and Medicine: Assessing the
20 Science Base*, 1999) have declared cannabis/marijuana "dangerous
21 to health."

22 Since the decision as to what is or what is not medicine
23 rests with the FDA, the Controlled Substances Act (§ 801 et seq.)
24 did not transfer or otherwise diminish the FDA's authority and
25 responsibility to determine whether a product is a "new" or
26 "exempt" drug or medicine under the grandfather clause:

27 "Clearly, the Controlled Substances Act does not
28 authorize the Attorney General, nor by delegation the
29 DEA Administrator, to make the ultimate medical and
30 policy decision as to whether a drug should be used as
31 medicine." ... "The FDA has both the experts and the
32 statutory mandate to resolve conflicts over safety and
33 efficacy of new drugs."

34 57 Fed.Reg. 10499, 10505 (1992)

35 D. HEARING REQUESTED/REQUIRED PRIOR TO ANY ADVERSE RULING

36 As noted above, as more fully set forth in the attachments,
37 there are genuine and substantial issues of fact regarding the
38 exempt status of the products listed in this petition. As such,
39 a full hearing is required prior to any adverse ruling on the
40 issues contained within this petition. See 21 CFR § 12.87(a)
41 ("The objective of a formal evidentiary hearing is the fair
42 determination of relevant facts consistent with the right of all
43 interested persons to participate and the public interest in
44 promptly settling controversial matters affecting the public
45 health and welfare.").

46 In controversial matters affecting the public health and
47 welfare, the Commissioner of the Food and Drug Administration is


1 required to produce a "full administrative record" which includes
2 a "full hearing" to give "proponents an opportunity to express
3 their views." *Rutherford*, 542 F.2d. at 1143; accord *Breitmeyer v.*
4 *Califano*, 463 F.Supp. 810, 815 (E.D.Mich 1978) ("Under 21 CFR §
5 314.200(d), any interested person may request a hearing. The
6 hearing, once granted, would extend to all issues relating to
7 [the product's] status as a new drug, including exemption under
8 the grandfather clause. 21 CFR § 314.200(e)(2).").

9
10 **E. CERTIFICATION and VERIFICATION**


11 The undersigned certify, that, to the best knowledge and
12 belief of the undersigned, this petition and notice of exemption
13 includes all information and views on which the petition relies,
14 and that it includes representative data and information known to
15 the petitioners which are both favorable and unfavorable to the
16 petition.

17 The undersigned verify that all appropriate records have
18 been searched and to the best of their knowledge and belief it
19 includes a true and accurate presentation of the facts.

20 Signed:

21 
22 _____
23 Paul Kloppe
24 c/o Pharmacy
25 Post Office Box 242
26 Forestville, CA 95436
27 707/568-0945

Dated: May, 21, 1999

28 
29 _____
30 Tod H. Mikuriya, M.D.
31 1168 Sterling Avenue
32 Berkeley, CA 94708

Dated: May, 21, 1999

TO: DOCKETS MANAGEMENT BRANCH
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

PETITION and NOTICE OF EXEMPTION

INDEX TO ATTACHMENTS

<u>TAB</u>	<u>DESCRIPTION</u>
A	PARKE, DAVIS & CO.
B	ELI LILLY & COMPANY
C	MERCK
D	SQUIBB
E	APEX/FEDERICK STEARNS & CO.
F	DISPENSATORY OF THE UNITED STATES OF AMERICA (1937)
G	PHARMACOPOEIA OF THE UNITED STATES OF AMERICA (1926)
H	MATERIA MEDICA: PHARMACOLOGY: THERAPEUTICS PRESCRIPTION WRITING FOR STUDENTS AND PRACTITIONERS (1914)
I	MATERIA MEDICA AND PHARMACOLOGY (1927)
J	THERAPEUTICS MATERIA MEDICA AND PHARMACY (1926)
K	POCKET THERAPEUTICS AND DOSE-BOOK (1910)
L	PHARMACOPOEIA OF THE UNITED STATES (1936)
M	REMINGTON'S PRACTICE OF PHARMACY (1936)
N	A TEXT-BOOK OF PRACTICAL THERAPEUTICS (1916)
O	TEXTBOOK OF MATERIA MEDICA (1931)
P	TEXTBOOK OF MATERIA MEDICA (1928)

PO Box 242
Forestville, CA 95436

.....
FARMACY

June 11, 1999

DOCKETS MANAGEMENT BRANCH
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

FAX: 301/827-6870

Attn: Ms. Jeni Butler

Re: "Petition and Notice of Exemption" dated May 21, 1999

This will confirm that this petition is *categorically excluded* from the
"Environmental impact" category.

Again, thank you very much for your courtesy and cooperation in this
matter. Should you have any questions or comments, do not hesitate to
contact me at (707) 568-0945.

Sincerely,



Paul Klopper

.....

*This document contains copyrighted material which maybe
viewed at:*

***DOCKETS MANAGEMENT BRANCH
FOOD AND DRUG ADMINISTRATION
5630 FISHERS LANE, ROOM 1061
ROCKVILLE, MD 20852***